



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Kable Davis, MS

From: Eric Bohnenblust, Ph.D., Entomologist

Secondary Review: Jennifer Saunders, Ph.D., Senior Biologist

Date: 2/9/2017

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 424675

Decision no.: Reregistration

Submission no: Reregistration

Action code: Reregistration

Product Name: Insect Shield Repellent Apparel

EPA Reg. No or File Symbol: 74843-2

Formulation Type: Permethrin Impregnated Clothing

Ingredients statement from the label with PC codes included:

Permethrin 0.52% PC: 109701

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate): 0.52% permethrin which should equate to 0.125 mg/cm²

Use Patterns: Permethrin treated clothing to repel mosquitoes, ticks, ants, flies, chiggers, and midges; specific fabric types are not provided

I. Action Requested: Review eight MRIDs submitted under Reregistration to support efficacy claims against mosquitoes, ticks, ants, flies, chiggers, and midges for permethrin treated apparel.

II. Background: The registrant submitted eight MRIDs submitted in response to PDCI-109701-26513 to support numerous efficacy claims against mosquitoes, ticks, ants, flies, chiggers, and midges for permethrin treated apparel. MRIDs 46898101 (DP 331804 and 424674) and 45751902 (DP 285605 and 424674) were previously reviewed; the conclusions from DP 424674 as they pertain to EPA Reg. No 74843-2 are summarized below. MRIDs 46890402, 46976101, 46976102, and 46976103 were also reviewed under DP 331804. Detailed methods and results for MRIDs 46898101 and 46890402 can be found in the previous review for DP 331804, brief summaries of the methods, results, and current conclusions as they pertain to EPA Reg. No. 74843-2 can be found below. In addition, MRID 47210601 was previously reviewed (DP 344446); the methods can be found in the previous review but the results and conclusions based on this MRID are summarized below.

III. MRID Summary:

46898101. Justification for an In-vitro Test Methodology to Evaluate the Repellent Efficacy of Permethrin Incorporation into Textile Articles.

(1) **Conclusion: Unacceptable.** This study is not adequate to support efficacy or as justification to support in-vitro methodology for testing efficacy of impregnated clothes/fabrics against mosquitoes or other arthropods of public health importance. The registrant argues that because the presence of permethrin in garments does not equate with a prescribed level of performance and low levels of knockdown are often equated with high levels of bite protection, that only in-vitro bioassays using a 50% minimum threshold for knockdown are necessary to show efficacy of the impregnated fabric. However, the problem with using knockdown for an endpoint is that there is no clear relationship between knockdown and bite protection as stated in the justification provided by the registrant; therefore, the Agency cannot accurately determine whether the knockdown effect observed in the in-vitro bioassay proposed in this MRID is indicative of greater than the 90% bite protection threshold required to support efficacy claims. In addition, the proposed in-vitro method evaluates knockdown at 60 minutes after a 2-minute forced exposure; sixty minutes is more than enough time for a mosquito to bite a human. Numerous mosquito species will probe and take partial blood meals from multiple hosts (Klowden and Lea 1978, Grimstead et al. 1980, Scott et al. 1993). Moreover, probing behavior sometimes increases when mosquitoes are infected with arboviruses (Grimstead et al. 1980). Mosquitoes are capable of taking partial blood meals in much less than 60 minutes, probably even in less than the 2-minute exposure duration used in the in-vitro assays. Further, the effect of human hosts on the behavior of mosquitoes, ticks and other arthropods is also unclear and cannot be quantified using an in-vitro bioassay. Using knockdown bioassays against ticks is also problematic because of the forced exposure. If the clothing is repellent to ticks, they may be likely to drop off prior to a 2-minute exposure or crawl quickly across the fabric to exposed skin after latching on to a host. Importantly, some tick species (e.g., lone star ticks) may be able to crawl across a substantial length of fabric in under two minutes and reach exposed skin, so a 2-minute forced exposure is not necessarily realistic.

Another factor, not discussed in the MRID, is bite protection provided by different types of fabric. Fabrics with different material compositions, densities, and tightness of weave can provide different levels of physical protection from bites, indicating that the bite protection provided by a treated fabric product is potentially an additive combination of physical protection and efficacy of the permethrin treatment. Importantly, physical protection from bites provided by a fabric type cannot be evaluated using the in-vitro method. In addition to the issues with different fabrics and bite protection from mosquitoes, different fabric types may also result in different measures of repellency against ticks. In addition, the bio-availability of permethrin on different fabric types may vary, especially with regard to duration of efficacy because different fabrics are likely to age differently and the interaction of bite protection based on fabric type and permethrin amount cannot be assessed using in-vitro bioassays.

45751902. Buzz Off Insect Shield Apparel: Efficacy and Durability as a Repellent.

(1) non-GLP

(2) **Methods:** This MRID is a summary review document citing results of numerous studies evaluating efficacy of clothing impregnated with 0.52% permethrin. Numerous products containing the same use patterns are also cited as part of the summary. Also detailed is the amount of permethrin remaining after 50 launderings from a US Army study published in 1993. The document does not contain any methods or data showing efficacy against any public health pests. The citations section contains 20 MRID numbers; however, these MRIDs were not cited and therefore were not reviewed to support this product. Appendix I contains references to 12 products which are registered by EPA as either treated fabric products or products to treat fabrics. The PDCI request was for product specific data, none of which are contained in this MRID.

(3) **Results:** N/A

(4) **Conclusion: Unacceptable.** This MRID does not support any efficacy claims for EPA Reg. No. 74843-2. No product specific data are contained in MRID 45751902. A summary review is not adequate to meet the requirements for product performance data.

47210601. Buzz Off Insect Shield Insect Repellent Apparel Efficacy against Three Species of Mosquitoes and Two Species of Ticks.

(1) non-GLP

(2) **Methods:** See DP 344446 for a detailed summary of the methods for MRID 47210601.

(3) **Results:** Tables 1,2 below summarize the results for the species tested in MRID 47210601.

Table 1. Average Knockdown (KD) and % Resulting in $\geq 50\%$ KD of Mosquito Species in no-choice bioassay with Buzz Off Insect Shield Insect Repellent Apparel (samples from commercial production lots) (All results from 10 replicates per species).

No. washes	Aedes aegypti *			Culex quinquefasciatus		
	Avg % KD	Std Dev	% $\geq 50\%$ KD	Avg % KD	Std Dev	% $\geq 50\%$ KD
25	100.0	0	100	78.5	15.5	100
50	90.2	9.8	100	90.8	14.4	100
70	80.8	13.1	100	96.9	9.7	100
No. washes	Anopheles quadrimaculatus			Ochlerotatus taeniorhynchus		
	Avg % KD	Std Dev	% $\geq 50\%$ KD	Avg % KD	Std Dev	% $\geq 50\%$ KD
25	99.3	2.2	100	100	0	100
50	99.0	3.2	100	99.5	1.7	100
70	92.2	15.0	100	96.7	7.0	100

* Data for 50 and 70 washes excerpted from MRID 468904-02

Table 2. Average Knockdown (KD) and % Resulting in $\geq 50\%$ KD of Tick Species in no-choice bioassay with Buzz Off Insect Shield Insect Repellent Apparel (samples from commercial production lots) (All results from 10 replicates per species).

No. washes	Ixodes scapularis			Rhipecephalus sanguineus		
	Avg % KD	Std Dev	% $\geq 50\%$ KD	Avg % KD	Std Dev	% $\geq 50\%$ KD
25	100.0	0	100	100	0	100
50	100.0	0	100	97.6	3.9	100
70	100.0	0	100	95.8	10.6	100

(4) **Conclusion: Unacceptable.** As stated above (MRID 46898101), assays evaluating knockdown through forced exposure in Petri dishes are not adequate to support efficacy claims for impregnated fabrics against any public health pests. In addition, a 90% efficacy threshold is necessary to support label claims for any duration. Tests conducted with *Ae. aegypti* only show 80% efficacy through 70 washes, and, oddly, tests conducted with *Cx. quinquefasciatus* show less than 80% efficacy after 25 washes but over 90% efficacy after 50 and 70 washings. Further, for any efficacy claims against ticks, data should show efficacy against three species, lone star tick, deer ticks, and either brown or American dog ticks. Data for mosquitoes also should show efficacy against species from each of three genera, *Aedes*, *Culex*, and *Anopheles* mosquitoes. For more information on specific species of mosquitoes for testing please see <https://www.epa.gov/pesticide-registration/guidance-efficacy-testing-pesticides-targeting-certain-invertebrate-pests>.

46976101. Armed Forces Pest Management Board (AFPMD): Report of the Repellents Committee Meeting of November 16, 1987.

(1) non-GLP

(2) **Methods:** The first 16 pages of this report explains the topics discussed at the Armed Forces Pest Management Board meeting on November 16, 1987. Included are several short single paragraph summaries of studies conducted to assess efficacy and numerous other issues related to using permethrin treated uniforms. The summary paragraphs that pertain to permethrin treated uniforms are not detailed enough to assess and determine efficacy; therefore, this section does not support any efficacy claims for permethrin treated fabrics.

The next three sections contain more detailed reports of summary paragraphs presented in the first 16 pages. The first report (memo dated August 26, 1987) summarizes the health hazards associated with permethrin treated uniforms but does not contain efficacy data. The second report (memo dated September 23, 1987) also summarizes health hazards associated with the different application methods for treated military uniforms with permethrin and does not contain any efficacy data. The third report (memo dated November 6, 1987) also summarizes health hazard data for different application methods. The third report also contains a paragraph (page 35, paragraph c) documenting efficacy of the treated uniforms against *Culex* spp. mosquitoes and lone star ticks. Protection against mosquitoes was 86% with most bites occurring on the hands and against ticks the uniforms provided 99.8% "protection." The data contained in these reports are either not efficacy data or are not presented in sufficient detail to support efficacy claims for EPA Reg. No. 74843-2 or any other permethrin treated product.

The last section of the MRID contains a report to the Repellents Committee documenting two field studies and an arm-in-cage lab study. These studies were conducted with permethrin impregnated clothing and some repellents in addition to a control treatment. The first two studies were conducted using BDU (Battle Dress Uniforms) fabric and the third study tested a khaki uniform shirt donated by the Pakistani army. The arm-in-cage tests utilized 2 BDU fabrics (assumed 100% cotton or 50%:50% nylon/cotton). Fabrics were treated with 5 dosages and washed up to 50 times. Sample sizes and numerous other methods were not provided.

(3) **Results:** Results are not provided for the agenda overview and the health hazard reports. In the report for the Repellents Committee, bite protection provided by the Battle Dress Uniforms (BDU) was 99.8% in the field study. In the field study testing the shirt provided by the Pakistani army, people wearing the untreated shirt received two fewer bites per minute than those wearing treated shirts. Results from the laboratory study were variable and only provided for 50 washings. The results for the 0.125 mg permethrin/cm² dose which should pertain to treated articles containing 0.52% permethrin are presented as follows: for *Aedes aegypti* and *Aedes taeniorhynchus*, bite protection was over 90% through 20 washings on 100% cotton BDUs and the 50/50 ny:co blend; for *Anopheles albimanus*, bite protection was over 90% through 20 washings on 100% cotton BDUs and for 40 washings on the 50/50 ny:co blend; for *Anopheles quadrimaculatus*, bite protection reached 90% through 5 washings for 100% cotton BDUs and was over 90% for 20 washings for the 50/50 ny:co blend.

(4) **Conclusion: Unacceptable.** The first four sections do not contain any efficacy data. The last section is not acceptable because sample size was not provided for any of the studies, the fabric apparel types treated and sold under EPA Reg. No. 74843-2 are not indicated on the label and therefore cannot be directly compared to the tested fabrics, the type of control treatment and replication used to calculate percent bite protection is unclear, and the methods for confirming bites are not provided, in addition to an overall lack of experimental methods. In the third field study, the tested treatment was less effective than the control treatment. The Agency will not bridge data collected testing treated military uniforms to consumer apparel, without adequate justification. Different fabrics with different densities and weaves in addition to other physical properties affect the efficacy of different fabrics.

46976102. Final Report to the US Army Medical Research and Development Command for Field and Laboratory Testing of a Clothing Impregnant and Extended Duration controlled Release Repellent Formulation as Personal Protection against Biting Arthropods of Military Importance.

(1) non-GLP

(2) **Methods:** The efficacy of permethrin treated clothes was tested two ways, no-choice knockdown bioassays with mosquitoes (*Anopheles albimanus*, *Aedes aegypti*, and *Aedes taeniorhynchus*) and lone star ticks, and free-choice bioassays with human arms with mosquitoes. Free-choice bioassays were not conducted with lone star ticks. For mosquitoes, adult female specimens were used and for ticks, nymphs were tested.

No-choice tests: Tests were conducted by exposing 5 mosquitoes to treated or untreated fabric on a tabletop for 90 seconds. After 90 seconds, mosquitoes were transferred to an untreated filter paper and observed for knockdown at

15 and 60 minutes, and 24 hours post exposure. Tests were replicated three times for mosquitoes and two times for ticks with fabric from different locations on each fabric sample. Efficacy against lone star ticks was tested the same way, except that ticks were exposed to treated fabric for 2 minutes. The no-choice assays were conducted with 50%:50% nylon:cotton temperate weight BDUs and 100% cotton tropical weight BDUs treated at 0.125 mg permethrin/cm² and 0.25 mg permethrin/cm². The uniforms were treated using the hot dye bath, field laundry, cold water dip, pad roll, or spray-on application procedures. No-choice testing was conducted on uniforms washed up to 15 times.

Free-choice tests: Tests were conducted with the same fabrics used in the no-choice tests. Fifteen adult female mosquitoes of a single species were exposed to treated or untreated fabrics on a human thigh for 15 minutes according to the methods outlined in ASTM Standard B951-83 (protocol not provided). During the 15-minute exposure period, observations were made of landing, probing and biting behavior in 1.5 and 15 minutes. After exposure, mosquitoes were removed from the fabric treatment and observed for knockdown at 15 and 60 minutes and 24 hours post-exposure. As written, mosquitoes appear to have been removed from the test fabric (treated or untreated) itself and not the cages. Tests were replicated 3-5 times on the original unwashed treated fabric and fabric washed up to 10 times. The text is unclear as to whether replicates are different human subjects, different fabric swatches on the same human subject, or some other form of replication. Mosquitoes were tested using bare skin initially to qualify test mosquitoes. The control treatment consisted of untreated fabric.

(3) **Results:** All results are presented only for the application rate of 0.125 mg permethrin/cm²; the rate which equates to 0.52% permethrin.

No-choice tests: While effects were observed at 15 minutes and 24 hours post exposure, these effects were not reported. Therefore, all knockdown results are indicative of knockdown at 60 minutes post exposure. For all application methods and both uniform types (100% cotton, 50:50 ny:co), knockdown of all mosquito species was 90% or greater through 2 washings with the exception of impregnation using the cold dip method when tested against *An. albimanus* for which knockdown was greater than 90% through 5 washing cycles. For Lone star ticks, knockdown was over 90% through all wash cycles tested except when fabric was impregnated via the hot dye bath method. For the hot dye bath method, only exposure to unlaundered treated fabric resulted in 90% knockdown.

Free-choice tests: In the free-choice tests, over 90% bite protection against all three mosquito species was observed through all tested wash durations for both fabric types. Knockdown results from the free-choice bioassays were highly variable, ranging from less than 0% to nearly 100%.

(4) **Conclusion: Unacceptable.** The methods used to apply permethrin in this study are not applicable to the method used to impregnate fabric for EPA Reg. No. 74843-2. Method of impregnation can affect the durability of the treatment, therefore, data fabric impregnation methods should be product specific. In addition, the petri dish lab bioassays are not an acceptable method to determine efficacy of treated articles as stated above (MRID 46898101). Only one tick species, lone star ticks, was evaluated and data are required to show efficacy against deer ticks and either American or brown dog ticks in addition to lone star ticks. In addition, fifteen mosquitoes per cage is not adequate, and replication is difficult to decipher and not high enough for the free-choice tests. Also in the free-choice test, control data are not presented and we cannot discern how percent bite protection was calculated, how bites were confirmed, or if control data were used as a correction (e.g., Abbott's formula). The tested fabric types are no longer in use by the military, therefore, we are unable to discern which current uniforms would correspond with the BDUs although we assume the BDUs would correspond most closely with the Army Combat Uniform (ACU). The Agency will not bridge data collected testing treated military uniforms to support efficacy of consumer apparel without adequate justification. Different fabrics with different densities and weaves in addition to other physical properties affect the efficacy of different fabrics. In addition, the bite protection data presented in conjunction with knockdown data show no correlation between bite protection and knockdown. Thus, knockdown cannot be used to support bite protection efficacy because bite protection efficacy cannot be predicted using knockdown.

46976103. US Army Medical Research and Development Command for Field and Laboratory Testing of a Clothing Impregnant and Extended Duration Controlled Release Repellent Formulation as Personal Protection Against Biting Arthropods of Military Importance, Final Report 1987 Supplement to Final Report

1986, Part 1A Laboratory Bioassay of Permethrin Impregnation Procedures.

(1) non-GLP

(2) **Methods:** This study tested the bite protection efficacy against mosquitoes of permethrin impregnated (0.5% permethrin equating to 0.125 mg permethrin/cm²) and untreated BDUs made of 100% cotton or 50:50% nylon:cotton against *Ae. aegypti*, *Ae. taeniorhynchus*, *An. albimanus*, and *An. quadrimaculatus* mosquitoes. Testing was conducted using “small cage” and “stock cage” testing. Both methods are similar, but the main difference is that stock cages are larger than small cages. The larger cage size is thought to allow mosquitoes to behave more naturally. This study assessed efficacy of the fabrics treated by the pad roll, spray-on, and cold-water dip methods through 25 washings. Residue analyses were conducted on fabrics after each tested washing duration.

Small-cage assays: Tests were conducted with the same fabrics used in the no-choice tests. Fifteen adult female mosquitoes of a single species were exposed to treated or untreated fabrics on a human forearm for 15 minutes according to the methods outlined in ASTM Standard B951-83 (protocol not provided). During the 15-minute exposure period, observations were made of landing, probing and biting behavior at 15 minutes. After exposure, mosquitoes were removed from the fabric treatment and observed for knockdown at 15 and 60 minutes and 24 hours post-exposure. As written, mosquitoes appear to have been removed from the test fabric (treated or untreated) itself and not the cages. Replication is unknown. The text is unclear as to whether replicates are different human subjects, different fabric swatches on the same human subject, or some other form of replication. Mosquitoes were tested using bare skin initially to qualify test mosquitoes. The control treatment consisted of untreated fabric. Note that at least one page documenting methods for this study is unreadable.

Stock cage assays: Stock cage assays were conducted similarly to the small cage assays except that cages were much larger and inoculated with 200 female mosquitoes. Human arms were covered with treated or untreated fabric and placed into cages containing mosquitoes for 15 minutes. Knockdown counts were recorded at 15 and 45 minutes after initial exposure. At the count at 45 minutes post exposure, mosquitoes were counted and crushed to confirm blood feeding.

(3) **Results:** All results presented are applicable to an initial permethrin treatment rate of 0.125 mg permethrin/cm².

Small-cage assays: For the cold-dip application method, bite protection was variable, did not consistently reach 90% for any species after 20 or 25 washes, and was dramatically different for the two different fabric types. For the pad roll application method, bite protection was over 90% through 15 washes for all species and both fabric types. After fifteen washes, bite protection dropped below 90% for *Ae. taeniorhynchus* (cotton) and *An. albimanus* (cotton and ny:co). For the spray-on application method, bite protection never reached 90% for any species or fabric types and was very variable for different wash cycles. Knockdown was inconsistent and usually considerably less than 90% for all application methods, mosquito species, and fabric types.

Stock cage assays: For the cold-dip application method, bite protection for both fabric types was over 90% for all three species and all wash durations except for *Ae. taeniorhynchus* at 20 washings (cotton) where bite protection was 83% and *An. quadrimaculatus* at 0 washings (ny:co) when bite protection was 86%. For the pad roll application method, bite protection was over 90% for *Ae. aegypti* on both uniform types, *An. albimanus* on cotton BDUs, and *Ae. taeniorhynchus* on ny:co BDUs. For the fabric types not mentioned above, and *An. quadrimaculatus* for the pad roll application method efficacy hovered between 83-95% but was not consistently above 90%. For the spray-on application method, bite protection did not reach 90% for any species or fabric types. Knockdown was inconsistent and usually considerably less than 90% for all application methods, mosquito species, and fabric types.

(4) **Conclusion: Unacceptable.** The methods used to apply permethrin in this study are not applicable to the method used to impregnate fabric for EPA Reg. No. 74843-2. Method of impregnation can affect the durability of the treatment, therefore, data fabric impregnation methods should be product specific. In addition, the small cage test with fifteen mosquitoes per cage is not adequate, replication is not provided for the small-cage assay, and three replicates is not adequate for the stock cage assay. Also in the stock cage test, we cannot discern how percent bite protection was calculated, or if control data were used as a correction (e.g., Abbotts formula) or a measure to qualify mosquitoes for testing. The tested fabric types are no longer in use by the military, therefore, we are unable to

discern which current uniforms would correspond with the BDUs although we assume the BDUs would correspond most closely with the Army Combat Uniform (ACU). The Agency will not bridge data collected testing treated military uniforms to support efficacy of consumer apparel without adequate justification. Also, the Agency will not bridge data collected with BDUs to support efficacy of uniforms such as the fire resistant army combat uniform (FRACU) which have a more open weave. Different fabrics with different densities and weaves in addition to other physical properties affect the efficacy of different fabrics. In addition, the bite protection data presented in conjunction with knockdown data show no correlation between bite protection and knockdown. Thus, knockdown cannot be used to support bite protection efficacy because bite protection efficacy cannot be predicted using knockdown.

47830601. Buzz Off Insect Shield Insect Repellent Apparel: Small Sample Comparative Data: (Supplement).

(1) non-GLP

(4) **Conclusion: Supplemental.** The data contained in this supplement are pertinent to MRID 46890402 (below) and are reviewed in detail under that MRID below.

46890402. Buzz Off Insect Shield Insect Repellent Apparel: Duration of Performance.

(1) non-GLP

(2) **Methods:** This MRID consists of an in-vitro laboratory bioassay assessing knockdown of *Aedes aegypti* mosquitoes after a 2 minute forced exposure to 50:50 ny:co ACUs treated with permethrin. The Buzz Off Insect Shield application method was used with two different permethrin formulations and compared to an IDA application (rolled and placed in a treatment bag with 9 ml permanone) method using Permanone 40. Tests were conducted through 100 washings. In addition to knockdown of mosquitoes, fabrics were analyzed using GC to determine the amount of permethrin after different wash durations. The previous review of this MRID (DP 331804) considered additional information included in the supplement (MRID 47830601).

(3) **Results:** Control mortality was acceptable. Knockdown of *Ae. aegypti* at 60 minutes post exposure was 90% or higher through 40 wash cycles and over 80% through 70 wash cycles for almost all lots and fabric samples. Knockdown at 15 minutes post exposure did not reach 90%. Full results are presented in review for (DP 331804)

(4) **Conclusion: Supplemental.** The Petri dish lab bioassays are not an acceptable method to determine efficacy of treated clothing articles as stated above (MRID 46898101). This study tests the registered product and shows that the permethrin levels found on the treated military uniforms do have a biological effect against mosquitoes; however, studies evaluating bite protection should be conducted to support efficacy claims. The Agency will not bridge data collected testing treated military uniforms to support efficacy of consumer apparel without adequate justification. Different fabrics with different densities and weaves in addition to other physical properties affect the efficacy of different fabrics.

IV. EXECUTIVE DATA SUMMARY:

(A) The submitted data do not support any efficacy claims.

The Agency will not bridge data collected testing treated military uniforms to support efficacy of consumer apparel without adequate justification. Different fabrics with different densities, materials, and weaves in addition to other physical properties affect the efficacy of different fabrics. In addition, the impregnation processes, fabric types, and binder used to impregnate the permethrin onto the fabrics also affect the efficacy and duration of efficacy after launderings and other wear processes.

V. LABEL RECOMMENDATIONS:

(1) No use directions are acceptable. Data do not support efficacy of the product against any of the public health

pests listed on the label. There are no non-public health pests listed on the label.

(2) The following marketing claims are acceptable: none

(3) The following marketing claims are unacceptable: all listed marketing claims

(4) The following MRIDs should be removed from the data matrix, as they are classified as “unacceptable” to support the product: 45751902, 46890402, 46898101, 46976101, 46976102, 46776103, 47210601, 47830601

(5) See Notes below to PM/Reviewer regarding claims found on the label for EPA Reg. No. 74843-2:

(a) The following claims are considered product endorsements are not allowed under 40 CFR 156.10(a)(5):

The following agencies recommend permethrin treated apparel:

The U.S. Centers for Disease Control and Prevention (CDC), www.cdc.gov/travel

The World Health Organization (WHO), www.who.int National Institute for Occupational Health and Safety, www.cdc.gov/niosh/topics/lyme/

The American Academy of Family Physicians, <http://www.familydoctor.org>

The Public Health Agency of Canada, www.phac-aspc.gc.ca

Who recommends permethrin treated apparel?

The U.S. Centers for Disease Control and Prevention (CDC), www.cdc.gov/travel

The World Health Organization (WHO), www.who.int National Institute for Occupational Health and Safety, www.cdc.gov/niosh/topics/lyme/

The American Academy of Family Physicians, <http://www.familydoctor.org>

The Public Health Agency of Canada, www.phac-aspc.gc.ca

(b) Claims such as “neither insect shield apparel nor any other insect protection product can guarantee complete protection from insects or insect bites”, or “does not protect against diseases or reactions from insect bites” are not appropriate because they undermine the purpose of the product. These types of claims imply that the product will not prevent bites. Instead they should be replaced with claims such as “protects covered skin from biting mosquitoes.” In addition, claims against “diseases” are inappropriate. Any claims referencing diseases must mention specific diseases and be specific to pests listed on the label (e.g., repels mosquitoes which may transmit West Nile virus).

(c) Claims such as “No bugs, no bite”, “all buzz, no bite” imply 100% protection from bites and also contradict claims such as “does not guarantee complete protection from insects or bites”

(d) Efficacy claims/informative comments such as “In heavily infested areas, you may prefer to wear long-sleeved shirts and pants to increase protection” are inappropriate, and contradict efficacy claims noted above in section [V, 5(c)]. In addition, if information regarding wearing long sleeved clothing will appear on a label, additional statements such as “for permethrin impregnated clothing to provide protection from biting arthropods, the permethrin treated clothing must be worn as the outermost layer.” Permethrin is a contact toxicant which repels after the individual pest contacts the pesticide; therefore, if worn underneath long sleeve clothes the majority of biting pests are unlikely to contact the permethrin treated layer. Also, for short-sleeve garments, claims that the fabric repels ticks may need to be qualified by a statement such as “repels ticks that latch onto treated fabric;” claims of “repels ticks” are not appropriate because permethrin works through “excito-repellency” and will not repel ticks that latch onto bare skin.